APPARATUS AND METHOD FOR MANIPULATING A FLEXIBLE STRAND AND SOFT TISSUE REPLACEMENT DURING SURGERY

FIELD OF THE INVENTION

[0001] The present invention relates to endoscopic soft tissue replacement fixation. More particularly, the present invention relates to an apparatus and a method to reconstruct an anterior cruciate ligament with soft tissue replacements within a femoral tunnel.

BACKGROUND OF THE INVENTION

[0002] The knee joint is frequently the object of injury and is often repaired using arthroscopic surgical procedures. An example of such arthroscopic surgical procedure is the replacement of anterior cruciate ligaments of the knee. The tearing of these ligaments is common in sports activities such as football or skiing.

[0003] Currently, fascia lata soft tissue replacements are flexible strands which are affixed to a threaded stud and turned into the femoral tunnel. Unfortunately, this procedure may result in the soft tissue replacement being wrapped upon itself during insertion. Hamstring soft tissue replacements are also currently fixed over a screw in the tibial tunnel and fixed on the lateral femur. This technique requires the femoral tunnel to completely penetrate the femur. In addition, according to present procedures, fixation of the soft tissue replacement on the femoral side requires a large incision.

[0004] It has been difficult to insert and fasten a soft tissue replacement in a blind hole or tunnel. Attempts have been made to thread the soft tissue replacement through the tunnel and over an anchor, but with some difficulty. Thus far, the prior art has not developed a quick and efficient way to implant a soft tissue replacement over an implanted anchoring system.

[0005] While offering certain improvements in arthroscopic surgery to repair ligaments, the prior art may still be improved upon to overcome the limitations on the endoscopic hamstring soft tissue replacement fixation due, in many instances, to the weakness of the flexible strand used to span the gap between the tendon soft tissue replacement and the fixation post.

[0006] Other techniques attempt to use biological fixation to augment or replace mechanical fixation. While increasing fixation strength these techniques require time to fully realize their fixation potential. Additionally the techniques may take additional surgical time and resources that a purely mechanical fixation technique may not require.

SUMMARY OF THE INVENTION

[0007] An apparatus including a member that acts as a flexible strand insertion and guide rod is used to increase the simplicity and effectiveness of a soft tissue implant procedure. The member inserts a flexible strand, which has been preloaded onto the insertion rod, into a blind tunnel formed in a bone structure and provides a guide for a drill point or bit. Thus the member may be removed with the flexible strand already positioned in place to pull an implant into

the blind tunnel over the drill point. A cross or set pin is then pulled after the drill point into the drill hole to lock the implant in place.

[0008] A first embodiment includes an apparatus to position a flexible strand in a tunnel, having a diameter, formed in a bone while performing a surgery. The apparatus comprises a guide member extending along a first axis and having a first end and second end. The guide member includes a guide portion defining an area, extending from the first end and along the first axis. The guide portion includes a first leg and a second leg, the first leg and the second leg define a slot disposed therebetween, wherein the slot defines a first plane. The first leg further defines a first groove and the second leg defines a second groove; wherein the first groove extends along a distal end of the first leg and along a length of the first leg and the second groove extends along a distal end of the second leg and along a length of the second leg. The first groove and the second groove are adapted to receive the flexible strand. The first groove and the second groove define a second plane. The first plane and the second plane intersect within the area defined by the guide portion.

[0009] A second embodiment of the apparatus includes an apparatus to place a flexible strand in a tunnel, having a diameter, formed in bone while performing a surgery. The apparatus comprises a first member having a first end and a second end spaced apart. The first end defines a slot, adapted to guide an instrument, wherein the slot lies in a first plane. The first end further defines a groove, wherein the groove lies in a second plane. The first plane and the second plane intersect. A second member having a first end and a

second end, the second member defines a passage positioned adjacent the first end. The first member extends adjacent to the second end of the second member; wherein the first end of the first member and the passage are generally aligned.

[0010] A third embodiment includes a kit of surgical devices for performing arthroscopic surgery in tunnels, having a diameter, formed in bones. The kit comprises a guide system comprising a first member comprising a first leg and a second leg, a terminal end of said first leg defining a passage having a first axis. The kit further comprises at least one guide member extending along a second axis having a first end and a second end, wherein the first end extends from a terminal end of said second leg, and wherein the first axis and the second axis are generally orthogonal. Also included is a guide portion extending from the second end of the at least one guide member wherein the guide portion defines an angularly disposed slot and groove. Additionally, a tunnel forming device adapted to form a tunnel in the bone and further adapted to be received through the passage and the slot.

[0011] The new apparatus allows a new and unique method of performing an implant procedure. A method of surgically implanting a soft tissue replacement for attaching two bone members comprises inserting an insertion rod having a flexible strand pre-loaded on the insertion rod into a first tunnel. Next, forming a second tunnel transverse and through the first tunnel and the insertion rod with a tool bit. Next, retaining the flexible strand within the first tunnel. The method also includes removing the insertion rod from the first tunnel.

[0012] Further areas of applicability of the present invention will become apparent from the detailed description provided hereinafter. It should be understood that the detailed description and specific examples, while indicating the preferred embodiment of the invention, are intended for purposes of illustration only and are not intended to limit the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The present invention will become more fully understood from the detailed description and the accompanying drawings, wherein:

[0014] Figure 1 is a perspective view of the bone insertion rod affixed to a U-Guide;

[0015] Figure 2 is a perspective view of bone insertion rod not affixed to the U-Guide;

[0016] Figure 3 is an exemplary view of a knee prepared for insertion of the insertion rod;

[0017] Figure 4 is a perspective view of the insertion rod and U-Guide inserted into the tibia and femur tunnels with the flexible strand in place;

[0018] Figure 5 is a view of the U-Guide and insertion rod in place with a K-Wire Drill Point forming a transverse tunnel;

[0019] Figure 6 is perspective view of the K-Wire Drill Point with the flexible strand affixed to a soft tissue replacement and draped over the K-Wire Drill Point;

[0020] Figure 7 is a perspective view of the soft tissue replacement pulled over the K-Wire and out through the tibial tunnel;

[0021] Figure 8 is a perspective view of the soft tissue replacement in place and the ACL Cross Pin set in place in the transverse tunnel in the femur; and

[0022] Figure 9 is a deep view of the knee with an ACL replacement having its free ends affixed to the tibia and the femoral end affixed over the ACL Cross Pin.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0023] The following description of the preferred embodiment(s) is merely exemplary in nature and is in no way intended to limit the invention, its application, or uses. Moreover, while the present invention is discussed in detail below with regard to ACL reconstruction, those skilled in the art will recognize the other types of soft tissue fixation may employ the present invention.

[0024] Referring to Figure 1, a generally guide apparatus 10 which may be generally a U-shaped guide or a U-Guide generally includes an L-shaped retaining bar or L-guide 12 which includes two portions or legs, a first portion 14 and a second portion 16, that is substantially perpendicular to the first portion 14. The first portion 14 defines a guide section 18, having a guide section ledge 18a, formed transversely through the first portion 14. The guide section may be passage through or transverse to the first portion 14 such as a bore wherein the guide section ledge would be a bore ledge. A set screw 20 is provided to create

a locking mechanism for the guide section 18. The second portion 16 defines a bore 22 formed transversely through the second portion 16. Also, a flexible strand notch or flexible strand retaining member 23 is formed near the bore 22 on the second portion 16. A second set screw 24 is also provided to create a locking mechanism for the bore 22. The L-guide 12 is shown in an L-shape, however, it will be understood the L-guide 12 may be any appropriate form. Generally, however, the axes defining the guide section 18 and the bore 22 are orthogonal. Therefore, the first axis A of the guide section 18 should intersect the second axis B of the bore 22 at a right angle at a position.

[0025] An insertion or guide rod 26 is adjustably held in the bore 22 and locked in place with the second set screw 24. With continuing reference to Figure 1 and further reference to Figure 2, the insertion rod 26 includes a body portion 28. The body portion 28 is substantially cylindrical and formed around a longitudinal axis C. The body portion 28, which is generally a solid, may also taper towards the guide portion 36 (described herein). Also, the body portion 28 may include depth indicia 29 to give a visual indication of the depth of the insertion rod 26 into a patient.

[0026] Extending from a first end of the body portion 28 is an L-Guide engaging portion 30 which includes a notch or projection 32 that is received in the second portion 16 of the L-Guide 12 to ensure proper orientation of the insertion rod 26 to the L-Guide 12. The notch 32 on the insertion rod 26 is keyed to be received on to a portion of the second portion 16. The insertion rod 26 further includes a collar 34, having a first shoulder 34a and a second shoulder

34b, to ensure that the insertion rod 26 is held at a predetermined depth in the L-Guide 12 and to further ensure proper orientation of the insertion rod 26 relative to the L-Guide 12.

[0027] A guide portion 36 extends from a second end of the body portion 28. The guide portion 36 includes two generally parallel legs 38 and 40 and a shoulder 41. Each leg 38, 40 extends from the body portion 28 along axis C, though offset therefrom. The two legs 38, 40 define a slot 42, where the slot 42 extends substantially the distance of the two legs 38, 40 and has a slot ledge 42a where the two legs 38, 40 meet at the shoulder 41.

[0028] Also formed in each of the legs 38, 40 is a flexible strand groove 44. The flexible strand groove 44 may be any appropriate depth, but exemplary is substantially equal in depth to the diameter of a cord or flexible strand thread to be used with the apparatus 10. The flexible strand groove 44 extends, along the outside of each leg 38, 40, substantially the length of the legs 38, 40 and also over the distal end of the legs 38, 40. The flexible strand groove 44 also extends generally along axis C, though offset therefrom, and also over the terminal end of each leg 38, 40. The plane defined by the slot 42 is substantially orthogonal to the plane defined by the flexible strand groove may lie on any relative plane as long as the two planes intersect within the area defined by the guide portion 36. As described herein, a tool may be placed through the slot 42 while a cord is placed over the slot 42 by being positioned in the flexible strand groove 44.

[0029] The insertion rod 26 may be any desired length. Preferably, however, the distance between the second collar shoulder 34b and the slot ledge

42a is equal to the distance between a first end of the first portion 14, generally represented by line D, and the guide section ledge 18a. In this way, the guide section ledge 18a and the slot ledge 42a are generally equidistant from the second portion 16. Therefore, any instrument received through the guide section 18 would remain substantially parallel to the second portion 16 when it passed through the slot 42.

[0030] The flexible strand groove 44 is placed orthogonally to the slot 42 so that a cord, such as a flexible strand, may be placed in the flexible strand groove 44 to form an enclosed passage for any device that may be placed through the slot 42. In this way, a device such as a K-Wire (described herein), when inserted through the slot 42a has a flexible strand looped over the K-Wire. It will be understood, however, that the flexible strand groove 44 may be formed at any orientation relative to the slot 42 as long as a flexible strand placed in the flexible strand groove 44 will overlay the slot 42.

[0031] The notch 32 ensures that the insertion rod 26 is properly oriented with the L-Guide member 12 of the U-guide apparatus 10. In particular, the slot 42 is preferably aligned with the guide section 18. The set screw 24 tightens against the L-Guide engaging portion 30 to ensure that the insertion rod 26 does not move during a surgical procedure. Also, this ensures the proper keyed fit of the notch 32 into the second portion 16 so that the guide section 18 and the slot 42 are properly aligned. This ensures that the instrument received through the apparatus 10 is aligned. It will be understood, however, that any

appropriate means may be used to secure the insertion rod 26 to the L-Guide member 12 of the apparatus 10.

[0032] Referring to the remaining Figures 3-9, an exemplary method for using the apparatus 10, including the insertion rod 26 is described. It will be understood that although the apparatus 10 is described in the use of an Anterior Cruciate Ligament (ACL) replacement, any appropriate surgery may be performed with the apparatus 10 which would require its attributes.

[0033] With particular reference to Figure 3, a knee 50 generally includes at least a tibia 52 and a femur 54 surrounded by soft tissue 55. The knee 50 is initially prepared by forming a tibial tunnel 56 and a femoral tunnel 58 which are substantially in line with one another such that a straight and solid object could engage both the tibial tunnel 56 and the femoral tunnel 58 without a substantial amount of stress when the knee is placed in flexion between about 30 degrees and 110 degrees. It is understood that incisions must first be made in the soft tissue 55 surrounding the tibia 52 such that a tool may engage the tibia 52 and the femur 54 to form the tibial tunnel 56 and the femoral tunnel 58. Any suitable tool may produce the respective tunnels 56, 58 such as a pneumatic or electric drill or reamer. It is also understood that the femoral tunnel 58 is a blind tunnel. A blind tunnel is a tunnel which includes an entrance but no discernable exit, rather a blind tunnel terminates below the surface of the femur 54.

[0034] The size of the tibial tunnel 56 and the femoral tunnel 58 depends upon the size of the soft tissue replacement (described further herein) to be implanted into the patient. The larger the replacement needed, the larger

the diameter of the tibial tunnel 56 and the femoral tunnel 58. The tibial tunnel 56 and femoral tunnel 58 may be of any required diameter, but are generally between about 5 and 18 millimeters. It would be understood, however, that if a larger diameter replacement is necessary, then larger diameter tunnels 56, 58 may be produced in the tibia 52 and femur 54 to receive the implant. Additionally, smaller tunnels 56, 58 may be used if only a smaller implant is necessary. In addition, the largest area of the insertion rod 26 will have a diameter substantially equal to the diameter of the tibial tunnel 56 and femoral tunnel 58. For example, if the insertion rod 26 was produced so that the guide portion 36, in particular the shoulder 41, form the largest diameter of the insertion rod 26, then the outside diameter of the guide portion 36 would be substantially equal to diameter of the tibial tunnel 56 and the femoral tunnel 58. Also, the body portion 28 may have a lesser diameter, or a taper towards the shoulder 41, to ease insertion and removal of the insertion rod 26. This ensures that the insertion rod 26, and particularly the slot 42, are substantially centered in the femoral tunnel 58 for the remaining procedure.

[0035] A flexible strand 62, having a trailing end 62a and a leading end 62b, is placed or pre-loaded into the flexible strand groove 44 and then the insertion rod 26 is inserted through the tibial tunnel 56 and into the femoral tunnel 58, as best shown in Figure 4 (see also Figures 1 and 2). The flexible strand 62 may be any generally known strand suitable to the purpose such as a mono- or poly-filament suture, a flexible wire, or cord made of any suitable material. The flexible strand groove 44 allows the flexible strand 62 to be inserted through the

tunnels 56, 58 without engaging the walls of the tunnels 56, 58. Generally the depth of the flexible strand groove 44 is at least equal to the diameter of the flexible strand 62. The flexible strand 62 is placed so that it reaches substantially to the end of the femoral tunnel 58 and the slot 42 creates an opening through the center of the femoral tunnel 58 through which an instrument may pass, while not interrupting the flexible strand 62 which has been inserted into the femoral tunnel 58 by the insertion rod 26. The flexible strand 62 is caught in the flexible strand notch 23. The flexible strand 62 is held in position during the insertion of the insertion rod 26 into the tunnels 56, 58 and during the remaining surgical procedure by the flexible strand notch 23. Any suitable means may be used to hold the flexible strand 62 in place relative to the L-Guide member 12 of the apparatus 10. The flexible strand notch 23, which holds the flexible strand 62 with friction, is merely exemplary of one appropriate means to hold the flexible strand 62 in place.

[0036] Once the insertion rod 26 has been inserted into the femoral tunnel 58, so that the flexible strand 62 is positioned properly, a device, such as a drill bit or point 70 is used to produce a transverse tunnel 72 in the femur 54. The transverse tunnel 72 is formed transversely to the femoral tunnel 58. The transverse tunnel 72 will include an insertion point 72a and an exit point 72b. It will be understood that an incision must first be made in the soft tissue 55 surrounding the femur 54, so that the drill bit or point 70 may engage the femur 54 to form the transverse tunnel 72. The drill point 70 may be powered by any appropriate device known in the art such as an electric or pneumatic drill.

Furthermore, additional guide units or bullets 74, such as the U-Guide bullet produced by Arthotek, Inc. of Warsaw, Indiana, may be used to ensure the proper orientation and depth of the drill point 70. The guide bullet 74 is inserted into the guide section 18 and held in place with the set screw 20 to ensure the drill point 70 is properly aligned with the slot 42 when producing the transverse tunnel 72. The transverse tunnel 72 is produced through the entire width of the femur 54 so that the drill point 70 exits the femur 54 producing the exit point 72b. This allows the drill point 70 to be removed through the exit point 72b at the appropriate time. While the apparatus 10 is still in place, a cannulated reamer (not shown) enlarges a portion of the transverse tunnel 72. The reamed tunnel 73 receives the pin 84 (described herein). The reamed tunnel 73 does not extend the length of the transverse tunnel 72.

[0037] After the reamed tunnel 73 is produced, the apparatus 10, is removed as particularly shown in Figure 6. Once the apparatus 10 has been removed, the drill point 70 remains in the transverse tunnel 72. A soft tissue replacement 80 is affixed to the trailing end 62a of the flexible strand 62. The soft tissue replacement may be any suitable replacement such as a hamstring portion, an allograft tissue replacement, a xenograft tissue replacement, or an artificial soft tissue replacement which may be produced from materials such as polymers or metal. After the soft tissue replacement 80 has been affixed to the trailing end 62a, the leading end 62b of the flexible strand 62 is pulled drawing the soft tissue replacement 80 first through the tibial tunnel 56 and then through the femoral tunnel 58 over the drill point 70 and back down the femoral tunnel 58

and out through the tibial tunnel 56. This produces a loop of the soft tissue replacement 80 over the drill point 70 inside of the femoral tunnel 58. After being looped over the drill point 70, the two free ends 80a and 80b of the soft tissue replacement 80 extend from the tibial tunnel 56 adjacent to the tibia 52.

[0038] After the soft tissue replacement 80 has been looped over the drill point 70, an ACL cross pin or pin 84 is pulled into place in the reamed tunnel 73. The drill point 70 generally includes an eyelet 86 which will allow the attachment of the pin 84 to the drill point 70. Generally, the pin 84 is attached to the eyelet 86 through a second flexible strand 88 or other appropriate means. After the pin 84 is attached to the eyelet 86, the drill point 70 is pulled through the transverse tunnel 72, through the loop of the soft tissue replacement 80 and out the exit point 72b. This pulls the pin 84 into position and fixes it within the transverse tunnel 72, as particularly shown in Figure 8. Once the pin 84 has been fixed in place in the transverse tunnel 72, the attached flexible strand 88 may be cut or otherwise disengaged from between the eyelet 86 and the pin 84. The drill point 70 is then freely removed from the transverse tunnel 72. This leaves the pin 84 lodged into the transverse tunnel 72 which may be locked in place with either portions of the pin 84 or through any other appropriate locking means. Although any appropriate means may be used to hold pin 84 in the reamed tunnel 73, the pin 84 may include a square end to hold pin 84 in place. The pin 84 may also be threaded such as the device described in U.S. Patent No. 5,674,224 entitled "Bone Mulch Screw Assembly For Industrial Fixation of

Soft Tissue Soft tissue replacements And Method For Using Same" to Stephen M. Howell et al. incorporated herein by reference.

[0039] Because the pin 84 has been lodged in the transverse tunnel 72, and the soft tissue replacement 80 is looped over the pin 84, only the free ends 80a and 80b need to be secured to the tibia 52 to complete the implantation. A staple 90 is used to affix the free ends 80a and 80b of the soft tissue replacement 80 to the tibia 52, as best shown in Figure 9. It will be understood, however, that any appropriate means may be used to affix the free ends 80a, 80b to the tibia 52 such as U.S. Patent No. 5,674,224 entitled "Bone Mulch Screw Assembly For Industrial Fixation of Soft Tissue Soft tissue replacements And Method For Using Same" to Stephen M. Howell et al.; U.S. Patent No. 6,280,472 B1 entitled "Apparatus And Method For Tibial Fixation Of Soft Tissue" to James A. Boucher et al.; and U.S. Patent No 5,931,869 entitled "Apparatus And Method For Tibial Fixation Of Soft Tissue" to James A. Boucher et al. each incorporated herein by reference. Once the free ends 80a and 80b of the soft tissue replacement 80 are affixed to the tibia 52, the soft tissue replacement 80 securely attaches the tibia 52 and the femur 54 substantially as a natural ACL would.

[0040] It will be understood that any appropriate means may be used to affix the soft tissue replacement 80 in the femoral tunnel 58. The pin 84 is merely exemplary of any appropriate device to affix the soft tissue replacement 80 in the femoral tunnel 58. Any commonly known screw or other fixation device may be used to fix the soft tissue replacement 80 in the femoral tunnel 58. It will

also be understood that the soft tissue replacement 80 may be pulled over the pin 84 after the pin 84 has been lodged in the transverse tunnel 72. In particular, if the pin 84 is smooth, the soft tissue replacement 80 may be pulled over the pin 84 without damaging the soft tissue replacement 80 itself. The drill point 70 is simply removed from the transverse tunnel 72 before the soft tissue replacement 80 is pulled into the femoral tunnel 58.

[0041] It will also be understood that the method for performing the described procedure may be altered but remain within the scope of the presently claimed invention. For example the flexible strand 62 may looped over the insertion rod 26 such that the two free ends 62a and 62b are on one side and a loop of the flexible strand is formed on the other side of the insertion rod 26. Thus the soft tissue replacement 80 may be affixed to both free ends 62a and 62b or placed through the loop and then pulled over the insertion rod 26.

[0042] The description of the invention is merely exemplary in nature and, thus, variations that do not depart from the gist of the invention are intended to be within the scope of the invention. Such variations are not to be regarded as a departure from the spirit and scope of the invention.